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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/087,190 | 02/28/2002 | Pia M. Challita-Eid | 511582003420 | 7796 |

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EXAMINER

BLANCHARD, DAVID J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1643

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,190

Applicant(s)

CHALLITA-EID ET AL.

Examiner

David J. Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 6,-7, 9-10, 12-13, 15, 48-49 and 54 is/are pending in the application.
- 4a) Of the above claim(s) 15,48,49 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 6-7, 9-10, 12-13 and 78-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-3, 5, 8, 11, 14, 16-47, 50-53 and 55-77 are cancelled.

Claim 9 has been amended.

Claims 15, 48-49 and 54 remain withdrawn from consideration as being drawn to non-elected inventions.

2. Claims 4, 6-7, 9-10, 12-13 and 78-82 are under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

4. The rejection of claims 4, 6-7, 9-10, 12-13 and 78-82 under 35 U.S.C. 112, first paragraph, as introducing new matter into the claims is maintained.

The response filed 12/1/2005 refers to items XI, XII, XIII, XIV and XV at pages 17-18 of the as filed specification (filed 2/28/02) and these items at pages 17-18 make direct reference to Figures 5-9 and the polypeptides encoded by the polynucleotides are disclosed in item XIX at page 18, line 29. Applicant notes that the as filed specification at page 33, line 23, which states that the amino acid sequence of a 121P1F1 protein as shown in Figs 2-3 can be analyzed to select specific regions of the 121P1F1 protein for generating antibodies, for example, hydrophobicity and hydrophilicity analyses of a 121P1F1 are used to identify hydrophilic regions in the 121P1F1 structure. At page 33, lines 28-34, the specification goes on to indicate that these analyses can be performed

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for hydrophilicity profiles, hydropathicity profiles, percent (%) accessible residues profiles, average flexibility profiles, and bet-turn profiles and identifies computer programs suitable for generating such profiles. Applicant concludes that the specific regions of SEQ ID NO:3 are identified for the purpose of antibody production as the portions of the polypeptide identified in Figures 5-9 form part of the disclosure of the invention and the statement "[t]he amino acid sequence of a 121P1F1 protein as shown in Figure 2 or Figure 3 can be analyzed to select specific regions of the 121P1F1 protein for generating antibodies" indicates that the purpose for identifying these regions is to produce antibodies. This has been fully considered but is not found persuasive. Applicant is relying on a broad disclosure to support the narrower limitations of the present claims without adequate guidance or direction to lead one skilled in the art to producing antibodies against the presently claimed portions of SEQ ID NO:3. Although the specification discloses some general categories for selecting regions of SEQ ID NO:3 for producing antibodies and the Figures provide general guidance with respect to regions for generating antibodies, these descriptions do not provide adequate guidance and direction leading the skilled artisan to the particular regions of SEQ ID NO:3 as presently claimed, i.e., amino acids 1-67, 78-169, 178-205, 1-22, 117-142, 21-57, 76-113 and 120-149 of SEQ ID NO:3 or any fragment of said regions at least 5 amino acids in length. In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967) makes clear, one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the

originally filed disclosure. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

For the reasons of record and reiterated above, the rejection is maintained.

5. The rejection of claims 4, 6-7, 9-10, 12-13 and 78-82 under 35 U.S.C 103(a) as being unpatentable over Tang et al (WO 01/53312) in view of Harlow et al (Antibodies, A Laboratory Manual, Chapter 5, pp. 75-76, 1988) is maintained.

The response filed 12/1/2005 argues that Tang does not single out any particular regions of SEQ ID NO:3188 for generating antibodies and applicant asserts that only by use of the disclosure of the instant application would one select the specific regions claimed for use in generating antibodies. Applicant states that Harlow is used to suggest raising antibodies to the N-terminus and the C-terminus of a protein, however, the sequence disclosed by Tang is missing the first 15 residues of SEQ ID NO:3 of the instant application. Since Harlow does not supply the missing 15 N-terminal amino acids, the combination of references cannot suggest making antibodies to the N-terminus of instant SEQ ID NO:3 and Harlow does not suggest raising antibodies against residues 178-205 of instant SEQ ID NO:3, only to the rather generic and imprecise "C-terminus" of a protein. This has been fully considered but is not found persuasive. Applicant is limiting the claims to limitations not recited in the rejected claims, i.e., the claims are not limited to and do not require that the antibody bind within

the N-terminal 15 amino acids of SEQ ID NO:3. Tang et al teach various antibodies and conjugates thereof to the polypeptide of SEQ ID NO:3188, which has 100% amino acid identity with residues 16-205 of SEQ ID NO:3, and the antibodies can be raised using a fragment of the polypeptide that comprises at least 6 amino acids and Harlow suggests that the N- and C-termini of a protein are useful as immunogen for producing anti-peptide antibodies that will bind the native protein and the smallest peptide that will consistently elicit antibodies that bind the original protein are 6 residues in length. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced antibodies to the protein of SEQ ID NO:3188 using an N-terminal (e.g., amino acids 16-22 of SEQ ID NO:3) or C-terminal peptide of at least 6 amino acids in length as immunogen (e.g., amino acids 199-205 of SEQ ID NO:3), which are antibodies raised against a fragment of SEQ ID NO:3 comprising at least 5 amino acids of a peptide selected from amino acid residues 1-67 of SEQ ID NO:3 or residues 178-205 of SEQ ID NO:3 as presently claimed.

For the reasons of record and reiterated above, the rejection is maintained.

Conclusions

6. No claim is allowed.
7. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



SHEELA HUFF
PRIMARY EXAMINER